



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/807,506	02/27/1997	VICTOR SMIT	8524/71226	5096

42798 7590 08/07/2008
FITCH, EVEN, TABIN & FLANNERY
P. O. BOX 18415
WASHINGTON, DC 20036

EXAMINER

BOESEN, AGNIESZKA

ART UNIT	PAPER NUMBER
----------	--------------

1648

MAIL DATE	DELIVERY MODE
-----------	---------------

08/07/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 08/807,506	Applicant(s) SMIT ET AL.	
	Examiner Agnieszka Boesen	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 94-111, 133 and 137-141 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 94-111, 133 and 137-141 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/28/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Amendment filed April 28, 2008 in response to the Office Action of January 23, 2008 is acknowledged and has been entered. Claims 94-111, 133, 136-141 are pending and under examination.

Information Disclosure Statement

The Information Disclosure Statement received April 28, 2008 been considered.

Claim Rejections - 35 USC § 102/ *Claim Rejections - 35 USC § 103*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejection of claims 94-103, 106, 107, 109, 110, 111, 137-141 under 35 U.S.C. 102(b) as being anticipated or in the alternative under 35 U.S.C. 103(a) as being obvious over Smit et al. (Biochemical and Biophysical research communications, 1992, Vol. 187. in IDS of November 14, 2007) **is maintained.**

Applicant's arguments have been fully considered but fail to persuade. Applicant argues that the cited art provides no reasonable expectation of success that modifications of a

Art Unit: 1648

cytokine would lead to antagonistic activity in which the IL-3 still has the ability to bind the target receptor. Applicant argues that it would rather been likely that modification of the zinc binding ability of IL-3 would lead to the inactivation of the molecule. Applicant cites a reference by Cunningham in support of his arguments. In response the Office notes that Cunningham teaches that Zinc is not required for binding of human growth hormone to the human growth hormone receptor however zinc is required for the tight binding of the human growth hormone to the human prolactin receptor (see abstract and page 1709). While modifying the zinc binding ability to human growth hormone may reduce or increase the affinity between the ligand and the receptor, there is no teaching in Cunningham's reference about the loss of binding ability of the ligand to its receptor. Because zinc is not required for binding between the ligand and the receptor the modification of the zinc binding ability to IL-3 would not lead to the inactivation of the molecule, however it would lead to a change in binding affinity (increase or decrease). The present claims are broadly drawn to a method of quantitative structure and function analysis of proteins or peptides comprising chemical modifications of amino acids wherein the modifications result in enhanced biological activity, enhanced stability, acquired antagonistic activity. The claimed methods comprise modifying amino acids that are involved in catalytic zinc binding activity. It would have been obvious to the skilled artisan that a modification of amino acids within proteins may either result in increased or decreased activity of the protein. It would have been obvious that modifying zinc binding center of IL-3 to increase zinc binding affinity would result in enhanced biological activity, as required by the present claims, because Smit teaches that zinc binding activity of IL-3 is involved in phosphorylation of IL-3 receptor. Reference by Cunningham cited by Applicant provides additional evidence that there would have

Art Unit: 1648

been an expectation of success that enhancing the binding of zinc to its catalytic center would increase the affinity of the ligand to its receptor, because Cunningham teaches that addition of zinc increased the binding human growth hormone to its receptor see page 1709). Thus in view of the foregoing the rejection is maintained.

Rejection of claims 94-100, 104-109, 133, 136, 137, 138, 140 and 141 under 35 U.S.C. 103(a) as being unpatentable over Smit et al. (Electrophoresis, 1994, Vol. 15, p. 251-254) in view of Smit et al. (Biochemical and Biophysical research communications, 1992, Vol. 187. in IDS of November 14, 2007) and Builder et al (US Patent 4,511,502) **is maintained.**

The rejection is maintained for the same reasons as discussed above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1648

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035.

The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Agnieszka Boesen, Ph.D./

Examiner, Art Unit 1648

/Stacy B Chen/

Primary Examiner, Art Unit 1648